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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/784,169

02/24/2004

Gholam A. Peyman

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09/27/2006

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EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3735

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/784,169

Applicant(s)

PEYMAN, GHOLAM A.

Examiner

david shay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 20, 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Applicant alleges that no new matter has been added, however the originally filed specification is silent regarding a “compound which is an adhesive” thus limiting the compound to that class of materials which is known as adhesives is new matter.

With regard to the Lindstrom reference, the use of an adhesive is clearly disclosed at column 3, lines 14-29. Further it is noted that the claim does not require that any particular portion of the inlay be coated. Clearly the adhesive of Lindstrom adheres the inlay to the cornea, such that the inlay is fixed in place over, and thus adhered at the area that intersects the main optical axis. Regardless of this, however, Lindstrom specifically cites the use of a coating of the entire surface of the implant with a “basement coating membrane material 54, such as hydrogel, fibronectin,...,Type IV collagen...” (see column 2, lines 49-51). Applicant’s attention is respectfully invited to paragraph [0181] of the originally filed disclosure, which applicant has asserted as the basis upon which the newly added claim language rests, which reads , in pertinent part: “coating 610 can be any organic polymer or compound with bonding properties such as **fibronectin, collagen**, vitronectin, or polysaccharide.” (see originally filed disclosure, page 36, lines 19-21, emphasis added). Thus, since Lindstrom employs the self same compounds as applicant for the coating, applicant’s assertion that the newly added claim language, which is set forth as based on the very compounds the originally filed disclosure recites, cannot avoid Lindstrom, which recites some of these same compounds.

With regard to the remaining arguments, these are all based on the purported deficiency of the Lindstrom reference. However, since Lindstrom is in fact not deficient, as set forth above, these arguments are not convincing. It is further noted that applicant’s argument the “the collagen of Kelman is not an adhesive and it is not in any way adhering anything together” is not

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convincing in view of applicant's own disclosure that collagen is a compound with adhesive properties.

The amendment filed June 20, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "coating a surface of the inlay with a compound, wherein the compound is an adhesive that adheres the inlay to the cornea at the area that intersects the main optical axis".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on "coating a surface of the inlay with a compound, wherein the compound is an adhesive that adheres the inlay to the cornea at the area that intersects the main optical axis".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because the exact meaning of the term "coating a surface of the inlay with a compound, wherein the compound is an adhesive that adheres the inlay to the cornea at the area that intersects the main optical axis" is unclear, in view of applicants express arguments that compounds specifically recited in the originally filed disclosure as exhibiting adhesive properties and set forth as the basis for the added language, are not adhesives.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-6, 11, 12, 16, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindstrom.

Lindstrom teaches a method such as claimed, see Figures 2, 3, and 5 and col. 1, line 65 to col. 4, line 2 in order to place the lens as in Figure 3, first and second surfaces would be created, forming a flap; coating the article before hand would allow the compound to dry.

Claims 1, 3, 8, 9, 19-26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindstrom in combination with Bronstein and Steele et al. Lindstrom teaches a method such as claimed included the equivalence of outlays and inlays. Bronstein teaches securing implants in place using e.g. collagen glue. Steele et al teach employing e.g. collagen to promote tissue adhesion in corneal implants. It would have been obvious to the artisan of ordinary skill to cover the implant of Lindstrom with e.g. collagen since thus will serve to secure it without sutures, as taught by Bronstein and will promote cell adhesion, as taught by Steele et

al; to coat the second surface, since this is merely a matter of choice and provides no unexpected result; and to form the coating from an amniotic membrane, since this is merely a matter of choice and provides no unexpected result, thus providing a method such as claimed.

Claims 7, 10, 27, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindstrom in combination with Bronstein and Steele et al as applied to claims 1, 3, 8, 9, 19-26, 28, and 29 above, and further in combination with Kelman et al. Kelman et al teach cross-linking collagen using ultraviolet light. It would have been obvious to the artisan of ordinary skill to cross-link the collagen coating using ultraviolet light, since this would also cross link the coating to the collagen of the stroma and, with respect to claims 30 and 31, to employ the light such that the cross-linking is completed in no more than 5 minutes, since this is not critical, is well within the scope of one having ordinary skill in the art (as applicant has provided no particular collagen preparation or UV light parameters to achieve this particular effect), and provides no unexpected result, thus producing a method such as claimed.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lindstrom in combination with Bronstein and Steele et al as applied to claims 1, 3, 8, 9, 19-26, 28, and 29 above, and further in combination with Peyman ('748). Peyman ('748) teaches forming intracorneal implants from organic or synthetic materials and the use of diffractive technology. It would have been obvious to the artisan of ordinary skill to employ the materials and diffractive technology of Peyman ('748) in the method of Lindstrom, since these materials are equivalent to the materials of Lindstrom and since the materials and technology are merely a matter of choice and provide no unexpected result, thus providing a method such as claimed.

Claims 13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindstrom in combination with Bronstein and Steele et al as applied to claims 1, 3, 8, 9, 19-26, 28, and 29 above, and further in view of Peyman ('185). Peyman ('185) teach the use of a combination of synthetic and organic material and ablating the inlay. It would have been obvious to the artisan of ordinary skill to form the inlay of the material of Peyman ('185) since these are equivalents, this is merely a matter of choice and provides no unexpected result, and to ablate the inlay, since this does not require the deviate is prefabricated, thus producing a method such as claimed.

Applicant's arguments filed June 20, 2006 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Applicant's arguments with respect to claims 30 and 31 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY
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GROUP 330